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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,274	12/11/2001	Randolf von Oepen	17601.32a.1.1	7012

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EXAMINER	
FINN, MEGHAN R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/015,274	VON OEPEN, RANDOLF	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 18-34* is/are pending in the application.

4a) Of the above claim(s) *1-13,18,20,22,24-26,28,29,31,32 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16,19,21,23,27,30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/10; 9/14/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Biotin as the first member, Streptavidin as the second member, Iodine-125 as the radioactive moiety and subspecies IIa, IId, IIe and IIg as the species of kits in the reply filed on October 11, 2010 is acknowledged.

Claims 1-13, 18, 20, 22, 24-26, 28-29, 31-32 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 11, 2010.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 112 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 09/303,849 and 09/442,591, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. There is no support for the invention as claimed. Neither of the parent applications have any support for either streptavidin or biotin and also lack support for use of the stent for inhibiting restenosis. **Thus the current effective filing date of this application is December 11, 2001.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14, 16, 19, 21, 23, 27, 30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amendment to the claims submitted February 02, 2010 applicant amended claim 14 to add "in a selected density and/or pattern" to describe the manner in which

the first member is immobilized to the surface. Applicant also adds the same language with regards to the second member. However applicant has no support in the originally filed disclosure for "selected density and/or pattern". This amendment presents new matter and lacks written description of the invention because applicant never discloses what such selected density and or patterns are and thus the claims lack written description of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14, 16, 19, 21, 23, 27, 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed above, applicant has amended claim 14 to add "in a selected density and/or pattern" to describe the manner in which the first member is immobilized to the surface. It is not clear what limitation this presents as it is not possible for one of skill in the art to determine if applicant meant to claim the binding pair being immobilized to the surface in any selected density or pattern or if there is only 1 density and pattern that has been selected and if so what that density and/or pattern is. If it's any selected pattern then how does this further limit? It is not clear to one of skill in the art what applicant is intending to add with this limitation.

Additionally, in claim 14 it is not clear if applicant is attempting to claim the presence of a dose of radiation or merely that the device is capable of receiving such

radiation with the language "for delivery of a selected dose of radiation to the implantation site in the patient vessel in a range from about 10^{-3} grays to about 1000 grays for inhibition of restenosis". One of skill in the art cannot tell if the radiation is required by the claim or if the device is merely required to be capable of receiving such radiation and if that is the case what makes it capable or what device would not be? Thus the metes and bounds of claim 14 are unclear and claims 16, 19, 21, 23, 27, 30 and 33 depend from claim 14 without clarifying these issues and thus claims 14, 16, 19, 21, 23, 27, 30 and 33 are rejected for failing to point out and particularly claim the subject matter which applicant regards as the invention.

Further, in claim 29 applicant claims the second member is capable of binding to the first member irreversibly, effectively irreversibly, or reversibly. It is noted that claim 14 requires the two members to be capable of binding and it will be either irreversible or reversible so it is not clear what applicant intends to further limit as any bonding is one of those and thus the claim fails to further limit the claim from which it depends from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 19, 21, 23, 27, 30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Weadock et al. (US 6,264,596, cited on applicant's IDS).

Claim 14 claims a kit for inhibiting restenosis comprising an intravascular medical device having a surface and a first member, applicant has elected biotin, which is immobilized on the surface. The kit further has a perfusion catheter with a radioactive moiety bound to a second member, applicant has elected streptavidin as the second member. Weadock et al. teaches intravascular stents with a first substance that has a high affinity for a second substance that is radiolabled (abstract). They teach that the first substance is immobilized on the surface of the stent (column 2, lines 20-30). They teach their stents for treatment of restenosis (column 1, lines 1-7) and teach that stents such as balloon-expandable ones and catheters with radioactive substances are known (column 1, 35-45) and they teach using their stent with biotin paired with avidin or streptavidin and teach that the two have a strong affinity for each other and they further teach that anti-ligand (either biotin or streptavidin) is radio-labeled with Iodine 131. They teach that the biotin can be the ligand and the streptavidin the anti-ligand (column 3, lines 42-55), which corresponds to applicant's claims where the streptavidin is the radio-labeled second member that can bind to the biotin. The stents of Weadock et al. have the same structure as applicant is claiming with biotin immobilized on the surface of the stent and streptavidin which is radiolabeled with a radioactive moiety that will bind to the first substance and they teach this system for treatment of restenosis. Thus claim 14 is anticipated by Weadock et al.

In claim 19 applicant claims that the catheter is a balloon perfusion catheter, a balloon-expandable stent such as that taught by Weadock et al. (column 1 , lines 35-45) is such a catheter and thus Weadock et al. anticipates claim 19.

In claims 21 and 23 applicant claims that the first member is immobilized to a coating covering at least part of the surface. Weadock et al. does not teach a coating, however applicant does not specify any specific type of coating and thus anything including the material of the stent itself can be the "coating" that covers at least part of the surface. In claim 23 applicant claims that the fist member is immobilized by one or more types of chemical bonds. Weadock et al. teach that the biotin can be immobilized on a metallic stent by chelating agent or a polymeric stent with a crosslinking agent, both of these form chemical bonds and thus claims 21 and 23 are anticipated by Weadock et al.

In claim 29 applicant claims the second member is capable of binding to the first member irreversibly, effectively irreversibly, or reversibly. As noted above, this fails to further limit. Weadock et al. teaches that the biotin and streptavidin bind together strongly and is essentially irreversible (column 1, lines 47-55) and thus Weadock et al. anticipates claim 29.

In claim 30 applicant claims that the second member is connected to the radioactive moiety via a molecular linker. Applicant never discloses what they mean by a molecular linker, but one of ordinary skill in the art would interpret that to be any link between two molecules. Weadock et al. teaches that the radioisotope are affixed to the anti-ligand by methods such as iodination (column 4, lines 22-35) and since streptavidin

and iodine are both molecules the link between them when they are affixed together is a molecular linker and claim 30 is anticipated by Weadock et al.

In claim 33, applicant claims that the first and second members can be enzymatically or chemically cleaved. Since Weadock et al. teaches the same first and second members as applicant they must be able to be enzymatically or chemically cleaved since they are the same compounds and thus claim 33 is also anticipated by Weadock et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 16, 19, 21, 23, 27, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock et al. (US 6,264,596, cited on applicant's IDS), in view of Muzykantov et al. (WO 99/45960).

Claims 14, 19, 21, 23, 27, 30 and 33 are anticipated by Weadock et al. as discussed above. Because Weadock et al. teaches each and every limitation of applicant's claimed invention, it must also render the invention obvious. Weadock et al. teaches stents for treatment and inhibition of restenosis with the same compounds,

biotin and radiolabeled streptavidin and thus claims 14, 19, 21, 23, 27, 30 and 33 are obvious over Weadock et al.

In claim 16 applicant claims specific radioactive moieties and applicant has elected Iodine-125. Weadock et al. teaches using a radiolabel on the second member, including streptavidin but they teach Iodine 131 (column 4, lines 20-25). Muzykantov et al. teach a method of enhancing intracellular delivery using biotin and streptavidin (abstract) and they teach that streptavidin has four high affinity binding sites for biotin and that this allows coupling of the biotin without loss of biological activity (page 6) and they teach using iodine 125 to radiolabel streptavidin administered via intravascular catheter (pages 11-12) and thus the use of iodine 125 to radiolabel streptavidin was known in the art and it would be obvious to one of ordinary skill in the art based on the focus specifically on streptavidin of Muzykantov et al. that Iodine 125 would be a good choice for a radiolabel on the streptavidin specifically. Thus claim 16 is unpatentable over Weadock et al. in view of Muzykantov et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Leslie A. Royds/
Primary Examiner, Art Unit 1614